

Amendments to the Drawings

Attachment: Replacement Drawing
Annotated Sheet Showing Changes

The attached sheet of drawings includes changes to Figure 44 showing a different type of shading so that the details are easier to understand.

REMARKS/ARGUMENTS

Applicant has carefully reviewed the Office Action mailed on July 8, 2008. Applicant respectfully traverses all objections, rejections, and assertions made by the Examiner. Claims 1-39 remain pending. Claims 1-16, 18, 23-28, 32, 33, 35, and 39 having been withdrawn from consideration, claims 17, 19-22, 29-31, 34, and 36-38 are currently under examination.

Drawings

On page 2 of the Office Action, the Examiner objected to the drawings under 37 CFR 1.83(a). In particular, the Examiner stated "[t]he drawings are objected to because of shading making details difficult to understand." Examiner did not state which drawings included objectionable shading. Applicant has amended Figure 44 to include a different type of shading that will make the details easier to understand. Applicant encloses herewith a set of replacement drawings, including Figure 44 as amended. Withdrawal of the rejection is respectfully requested. If the rejection is maintained, Applicant respectfully requests that the Examiner provides another Office Action pointing to which drawings include objectionable shading so that Applicant may adequately respond.

Obviousness-Type Double Patenting

On page 2 of the Office Action, claims 17, 19-22, 29-31, 34, and 36-38 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 26, and 47 of U.S. Patent No. 6,800,084 in view of Zucherman et al. (U.S. Patent No. 6,074,390).

Claims 17, 19-22, 29-31, 34, and 36-38 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 9, 17, and 25 of U.S. Patent No. 7,001,397 in view of Zucherman et al. (U.S. Patent No. 6,074,390).

Claims 17, 19-22, 29-31, 34, and 36-38 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 16 of U.S. Patent No. 7,108,705 in view of Zucherman et al. (U.S. Patent No. 6,074,390).

Applicant responds to this rejection by enclosing herewith terminal disclaimers in compliance with 37 CFR 1.321(c). Although not conceding the merits of this rejection,

Applicant respectfully submits that the terminal disclaimers overcome this rejection, and that such filing has no effect on patent term.

Claim Rejection(s) under 35 U.S.C § 102

On page 4 of the Office Action, claims 17, 19-22, 29-31, 34, and 36-38 were rejected under 35 U.S.C. § 102(b) as being anticipated by Zucherman et al. (U.S. Patent No. 6,074,390). This rejection is respectfully traversed.

Independent claim 17 recites:

17. (previously presented) A method of treating two adjacent vertebrae in a spine of a patient, comprising:

inserting an access device through a minimally invasive incision in the skin of the patient;

advancing the access device until a distal portion thereof is located adjacent the spine;

expanding the distal portion of said access device from a first configuration to a second configuration, the second configuration having an enlarged cross-sectional area at the distal portion thereof such that the distal portion extends across at least a portion of the two adjacent vertebrae;

delivering a motion preserving, stabilization device to a location between the two adjacent vertebrae through the access device.

As the Examiner is likely aware, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (MPEP § 2131) (emphasis added). Zucherman et al. do not appear to teach each and every element *as set forth in the claim* 17, and, therefore, cannot anticipate claim 17.

In particular, Zucherman et al. do not appear to teach at least the limitation of “expanding the distal portion of said access device from a first configuration to a second configuration” In contrast, the Examiner’s asserts on page 5 of the Office Action “that expanding the access device from a first configuration to a second configuration, does not preclude the use of additional devices placed over the access device, followed by removal of the access device resulting in an enlarged cross section.” Applicant respectfully disagrees and believes that Examiner mischaracterizes both claim 17 and the Zucherman et al. reference.

As to mischaracterizing claim 17, claim 17 recites “expanding the distal portion of said access device” As Examiner is likely aware, when interpreting claim language the words of the “claim must be given their plain meaning unless **>the plain meaning is inconsistent with< the specification.” *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (MPEP § 2111.01). The plain meaning of “expanding the distal portion of said access device” would seem to be that the access device’s distal portion is expanded. It would not seem to mean that a second access device having a larger diameter at its distal portion is inserted.

As to mischaracterizing Zucherman et al., they do not appear to teach “expanding the distal portion of said access device.” On page 4 of the Office Action, Examiner cites “(Figs. 39 and 40, col. 1, lines 26-49, col. 4, lines 18-28, col. 9, lines 13-67 and col. 10, lines 1-14)” as teaching this limitation. However, upon closer examination, Figures 39 and 40 do not appear to teach such expansion, in fact, they appear to suggest that a narrow distal portion is preferable. Col. 1, lines 26-49; col. 4, lines 18-28, col. 9; and col. 10, lines 1-14 do not appear instructive on the matter. And, col. 9, lines 13-67 actually appears to support Applicant’s position:

“Further, a plurality of cannula can be used instead of one, with each cannula being slightly bigger than one before. In the method of the invention, *the first smaller cannula would be inserted followed by successively larger cannula being place over the previous smaller cannula. The smaller cannula would then be withdrawn from the center of the larger cannula.* Once the largest cannula is in place, and the *opening of the skin accordingly expanded*, the implant, which is accommodated by only the larger cannula, is inserted through the larger cannula and into position.” (col. 9, lines 48-57) (emphasis added).

The Zucherman et al. method appears to teach expanding the opening of the skin not “expanding the distal portion of said access device.” Furthermore, the successively larger cannula could not be used to expand the distal portion of said access device because they are placed *over* the access device, and the access device is removed through the center of the larger cannula. Clearly, Zucherman et al. do not teach at least this limitation and therefore do not anticipate claim 17.

Also, Zucherman et al. do not appear to teach the limitation of “the second configuration having an enlarged cross-sectional area at the distal portion thereof such that the

distal portion extends across at least a portion of the two adjacent vertebrae” The device taught by Zucherman et al. does not appear to *extend across* at least a portion of the two adjacent vertebrae, but rather appears to be *inserted between* two adjacent vertebrae. (see Figs. 39-40; col. 9, lines 43-47). For at least the foregoing reasons claim 17 is believed patentable over Zucherman et al. Withdrawal of the rejection is respectfully requested.

Independent claim 19 recites:

19. (previously presented) A method of treating a spine of a patient, comprising:
 inserting an access device through a minimally invasive incision in the skin of the patient;
 advancing the access device until a distal portion thereof is located adjacent the spine;
 expanding the distal portion of said access device from a first configuration to a second configuration, the second configuration having an enlarged cross-sectional area at the distal portion thereof such that the distal portion extends across at least one of two adjacent vertebrae;
 delivering a stabilization device through the access device to a location between the two adjacent vertebrae, the stabilization device being configured to preserve motion between the two adjacent vertebrae.

For at least reasons similar to those mentioned above regarding claim 17, claim 19 is believed patentable over Zucherman et al. As claims 20-22, 29-31, 34, and 36-38 depend from claim 19 and include additional limitations, they are also believed patentable over claim 19. Withdrawal of the rejection is respectfully requested.

Claim Rejection(s) under 35 U.S.C § 103

On page 5 of the Office Action, claims 17, 19-22, 29-31, 34, and 36-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Zucherman et al. (U.S. Patent No. 6,074,390) in view of Davison et al. (U.S. Patent No. 6,187,000). This rejection is respectfully traversed.

As the Examiner is likely aware, “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (MPEP § 2143.01 IV). If one were to modify Zucherman et al. according to Davison et al., the principle of operation of

Zucherman et al. would change. The Zucherman et al. device appears to narrow towards its nose end (266) so that the cannula itself may be inserted between the vertebra: "[t]he cannula 258 is somewhat conical in shape with the nose end 266 being somewhat smaller than the distal end 268 in order to effect the *insertion of the cannula into the space between the spinous processes.*" (col. 9, lines 43-47) (emphasis added). On the other hand, the Davison et al. device appears broader to provide "a significantly larger working area for the surgeon inside the body 130 within the confines of the cannula." (col. 4, lines 39-42). For at least the foregoing reasons, Applicant respectfully asserts that a prima facie case for obviousness has not been made. Applicant believes that claims 17, 19-22, 29-31, 34, and 36-38 are patentable over Zucherman et al. in view of Davison et al. Withdrawal of the rejection is respectfully requested.

CONCLUSION

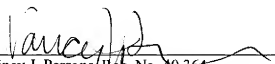
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
GENE DIPOTO

By his attorney,

Date: _____

9/4/08


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